

U.S. Appln. S.N. 10/828,351  
AMENDMENT

PATENT

REMARKS

This Amendment rewrites claim 23. The complete dissolution feature of the claimed method is supported by page 5, lines 13-18 of the specification. Claims 23-31 are pending.

Examiner Tran is thanked for indicating the allowability of claims 29 and 30. It is believed this Amendment places the entire application in condition for allowance for the reasons which follow.

A Transmittal of Terminal Disclaimer is attached. Reconsideration and withdrawal of the obvious-type double patenting rejection of claims 23 and 26-30 over claims 1, 2 and 5-12 of U.S. Patent No. 6,764,690 to Ahola et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 23-28 and 31 over U.S. Patent No. 5,591,453 to Ducheyne et al. in view of International Patent Publication WO 92/20623 to Einarsrud et al. is respectfully traversed. A feature of the claimed method of administering a biologically active agent into a human or animal body is the complete dissolution of a silica-xerogel carrier within a desired time period upon contact with body fluid. The silica-xerogel dissolves controllably, and release of the biologically active agent from the silica-xerogel is determined by this silica-

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xerogel dissolution (Specification, page 5, line 31 to page 6, line 5). The release rate is thus substantially independent of diffusion through the pores of the silica-xerogel. Controlled release of a biologically active agent through biodegradation of the carrier is particularly advantageous when the biologically active agent is a large molecule or even a particulate, and diffusion through the carrier is not an option. Yet another advantage is the silica-xerogel releases the biological agent in a very even fashion, as evidenced by Fig. 1 of this application.

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed method because the cited references fail to disclose or suggest the total dissolution of the silica-xerogel feature of the claimed method. As conceded by the Patent Office, Ducheyne et al. fails to disclose the silica-xerogel feature of the claimed method.

Ducheyne et al. also fails to disclose the total dissolution feature of the claimed method. More particularly, Ducheyne et al.'s controlled release is achieved primarily by diffusion of its bioactive agent through the pores of its silica-based glass rather than by dissolution of its carrier. See, for example, Col. 6, lines 15-17 ("In the case of pure silica glass, the release of the

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biological molecules from the carrier is effected primarily by diffusion through the pore structure"). Thus, the rate limiting factor in release of the biologically active agent is its diffusion through the pores of the silica-based glass carrier. One of ordinary skill in the art would understand the Ducheyne et al. carrier need not be dissolvable to achieve release of its biologically active agent.

Nowhere in Ducheyne et al. is carrier degradation or biodegradation disclosed as its primary release mechanism. Although Ducheyne et al. mentions resorption or degradation when discussing the prior art (Col. 4, line 6 and 26) and in the objectives to be met for a delivery system for biologically active molecule (Col. 3, lines 35-36), a careful reading of the reference makes clear that Ducheyne et al.'s release mechanism is primarily based on diffusion rather than dissolution of its silica-based glass carrier. In short, the reference always refers to controlling porosity of the carrier as a means of controlling release rate. See, for example, Col. 9, lines 16-18, and Col. 14, lines 33-39.

The deficiencies of Ducheyne et al. are not remedied by the additional disclosure of Einarsrud et al., which also fails to

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disclose or suggest the complete dissolution feature of the claimed method of administering a biologically active agent into a human or animal body. Instead, Einarsrud et al. discloses gels suitable for insulation, and its main emphasis is on obtaining gels with high porosity.

Reconsideration and withdrawal of the obviousness rejection of claims 23-28 and 31 over Ducheyne et al. in view of Einarsrud et al. are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 23-28 and 31, and issuance of a Notice of Allowance directed to claims 23-31, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

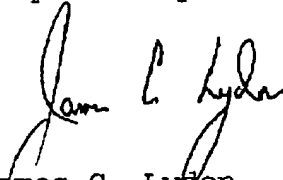
The Transmittal includes the disclaimer fee required by 37 C.F.R. § 1.321(b)(4). It is not believed any additional fee is required for entry and consideration of this Amendment.

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Nevertheless, the Commissioner is authorized to charge our Deposit  
Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,



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Enclosure:  
Transmittal of Terminal Disclaimer